



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,336	10/16/2003	John T. Kilcoyne	P-71486-US2	7853
49443 7590 08/08/2011 Pearl Cohen Zedek Latzer, LLP 1500 Broadway 12th Floor New York, NY 10036				
EXAMINER NGUYEN, HUONG Q				
ART UNIT 3736		PAPER NUMBER		
NOTIFICATION DATE 08/08/2011		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO@pczlaw.com
Arch-USPTO@pczlaw.com

Office Action Summary

Application No.

10/687,336

Applicant(s)

KILCOYNE ET AL.

Examiner

HELEN NGUYEN

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 50-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date 4/22/2011.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the amendment filed 5/23/2011. Claim 50 is amended. **Claims 50-60** remain pending and under prosecution.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 4/22/2011 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. **Claims 50-51 and 58-60** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anggiansah et al (Primary Peristalsis is the Major Acid Clearance Mechanism in Reflux Patients) in view of Johnsson et al (Determinants of Gastroesophageal Reflux and their Inter-relationships).

7. In regards to **Claim 50**, Anggiansah et al disclose a system for measuring physiological parameters in the body of a patient indicative of gastroesophageal reflux, the system comprising:
a monitoring device (pH catheter and pressure sensing catheter – p.1537 especially “pH measuring assembly” in right column), said monitoring device comprising a housing adapted to be implanted in the body of a patient by attachment to tissue inside the body (using micropore tape – p.1537 left column), wherein www.dictionary.com defines implant as “inserted into the body,” and a plurality of sensors (6 pressure transducers and pH electrode – p.1537 right and left column) included in said housing, wherein each of the plurality of sensors is capable of independently measuring a different respective physiological parameter indicative of gastroesophageal reflux, i.e. pH and pressure, and wherein said monitoring device periodically

transmits a signal indicative of the value of the respective physiological parameter measured by each of the plurality of sensors (monitoring at 8 samples/s – p.1537);

a receiver (recording device – p.1537 right column bottom) that receives the signals from the monitoring device, said signals representing measurements made by the respective plurality of sensors, monitors the physiological parameters indicative of gastroesophageal reflux based on at least the received pH signals, and is capable of determining at least the presence of gastroesophageal reflux based on said plurality of signals (p.1537 – left column).

8. However, Anggiansah et al do not expressly disclose that the determination of gastroesophageal reflux is based upon both the pH and pressure signals. Johnsson et al teach that pressure data is highly valuable in gastroesophageal reflux determination and is the single variable that correlates most strongly to the amount of reflux determined using at least pH monitoring, see at least abst, Table 1, first page left column. Anggiansah et al teach all the structural elements of the claimed invention except an express recitation of the determination of the gastroesophageal reflux is based upon both the pH and pressure signals. Since Johnsson et al teach that pressure data is so highly valuable in the determination of gastroesophageal reflux, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the determination of gastroesophageal reflux performed by Anggiansah et al be made with both pH and pressure signals, thus providing a recitation of the determination based upon each of said plurality of signals received from said plurality of sensors (pH and pressure) as suggested by Johnsson et al, to more accurately determine the presence and amount of gastroesophageal reflux in the patient due to a known correlation between pressure, pH, and reflux.

9. In regards to **Claim 51**, Anggiansah et al disclose at least one of said plurality of sensors includes a pH monitor (p.1537).

10. In regards to **Claim 58**, Anggiansah et al disclose the receiver (recording device) monitors a change in pH as a function of distance from a lower esophageal sphincter (p.1537 – left column).

11. In regards to **Claim 59**, Anggiansah et al in combination with Johnsson et al disclose said plurality of sensors include a pH monitor and an auxiliary sensor, wherein said auxiliary sensor is to measure an auxiliary physiological parameter that is not a pH parameter, i.e. pressure, wherein the receiver is configured and thus capable of receiving a pH reading from said pH sensor and to adjust said pH reading based on the measured value of the physiological parameter, see Figure 4 (p.1538-1542 – Anggiansah et al). Also see correlation of Johnsson et al.

12. In regards to **Claim 60**, Anggiansah et al disclose the auxiliary physiological parameter is selected from the group consisting of: an ion concentration, a temperature, and a pressure (p.1573 – left column).

13. **Claims 52-55** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anggiansah et al in view of Johnsson et al, further in view of Brune (US Pat No. 5984875).

14. In regards to **Claim 52**, Anggiansah et al as modified by Johnsson et al above disclose the plurality of sensors includes a pH monitor (Col.4: 64) but do not explicitly disclose said sensors include an RF transmitter and a microprocessor. Brune teaches the use of an RF transmitter 9,10 to transmit the signals from an analogous implanted sensor 2 (Col.6: 40-42). Brune also teaches analogous implanted sensor 2 includes a microprocessor 7 that periodically receives a signal from the sensor and induces the RF transmitter to periodically send an RF signal indicative of the sensor (Col.6: 22-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Anggiansah et al as modified by Johnsson et al so that the plurality of sensors include an RF monitor as an effective means to transmit the signal information wirelessly. Also, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the plurality of sensors of Anggiansah et al as modified by Johnsson et al and Brune to include a microprocessor that periodically receives a signal from the pH monitor and induces the RF transmitter to periodically send an RF signal indicative of the pH measured by the pH monitor as an effective means to periodically transmit the pH information signal.

15. In regard to **Claims 53-54**, Anggiansah et al as modified by Johnsson et al above and in combination with Brune disclose the plurality of sensors each with a microprocessor above but do not explicitly disclose the microprocessor enables the pH monitor during a first interval and then disables the pH monitor during a second interval, while the RF transmitter is enabled during the second interval and disabled during periods of each cycle other than the second interval. However, Brune does disclose a first interval which is defined as when the microprocessor 7

periodically enables the sensor to obtain a signal and a second interval which is defined as when the RF transmitter 9,10 is enabled to transmit the signal (Col.6: 35-42). Brune also teaches that battery life is conserved by disabling the respective functions i.e. keeping the sensor in sleeping mode until it is necessary to trigger the signals (Col.6: 32-35).

16. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Anggiansah et al as modified by Johnsson et al and Brune such that during the first interval the RF transmitter is disabled and during the second interval the pH monitor is disabled, wherein the disabling occurs when the respective function is not performed, i.e. the pH monitor of the respective sensor is disabled during periods of each cycle other than the first interval and the RF transmitter is disabled during periods of each cycle other than the second interval, as an effective way to enhance the battery life conservation by only enabling the proper function as it is being used and disabling it during all other times.

17. In regards to **Claim 55**, Anggiansah et al as modified by Johnsson et al above disclose the invention above but do not disclose each signal transmitted by the plurality of sensors includes an identifier that is indicative of the sensor from which the signal is sent. Brune et al disclose an analogous measuring system comprising sensors 2 that transmit a signal including an identifier code that is indicative of the sensor from which the signal is sent (Col.5: 49-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the signals sent from the implanted sensors of Anggiansah et al as modified by Johnsson et al an identifier code as taught by Brune to effectively differentiate the particular sensor from which each signal was sent.

18. **Claims 56-57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Anggiansah et al in view of Johnsson et al and Brune, further in view of Kumar et al (US Pat No. 6416471).

19. Anggiansah et al as modified by Johnsson et al and Brune above disclose the receiver (recording device) includes circuitry to sense the position of the patient and periodically records the position of the patient (p.1538 – right column – Anggiansah et al). However, Anggiansah et al in combination with Johnsson et al and Brune do not disclose the receiver worn by the patient. Kumar et al disclose an analogous receiver 20 worn by the patient best seen in Figure 1 as well as circuitry to sense a position of the patient (Col.11: 35-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the receiver of Anggiansah et al as modified by Johnsson et al and Brune to be worn by the patient as taught by Kumar et al for ease of transportation and monitoring without hindering patient activity.

Response to Arguments

20. Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection.

21. Regarding applicant's contention that the device of Anggiansah et al is not implanted by attachment to tissue inside the body, it is noted that wherein www.dictionary.com defines implanted as "inserted into the body," which as inserted into the throat of the patient, the catheter of Anggiansah et al is therefore inserted into the body and thus implanted for a period of time.

The tape used to secure the catheter even if placed outside the body nevertheless causes "attachment to tissue inside the body" of the patient. It is noted that the claims do not recite the location and nature of said attachment. It is further noted that the catheter of Anggiansah et al necessarily contains a housing structure on which said sensors above are placed. It appears that applicant is attempting to read the claims more narrowly than can be broadly and reasonably interpreted as recited. Therefore, the Anggiansah et al reference is maintained for said reasons elaborated above.

Conclusion

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736